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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,318	10/17/2001	D. Wade Walke	LEX-0255-USA	4962

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EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,318	WALKE ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-4 with new claims 6-9, on 9/7/04 is acknowledged. The traversal is on the grounds that the 35 nucleic acid and amino acid sequences are all encoded by a common genetic locus and can be properly included into a Markush group because all the sequences are splice variants of a novel human semaphorin protein and therefore share a common utility and substantial structural features. This is not found to be persuasive because the utilities of the broad generic class of proteins known as semaphorins are different between the sub-genii of known semaphorin nucleic acids and proteins. For example, some semaphorin proteins are known to be chemoattractant, i.e. these semaphorins promote the regeneration of axons of neurons, while other semaphorins are chemorepulsive, i.e. these semaphorins collapse growth cones and inhibit the axonal regeneration of neurons, so different semaphorins possess different utilities. In addition, semaphorins are known in the prior art to be a diverse gene family that *may or may not* share substantial structural features among their different members (see Püschel et al., Figure 2), so Applicant's assertion of such structural similarity is unsupported by either the prior art or the instant Application. Finally, searching separate and multiple databases for 35 different nucleic acid and amino acid sequences would create an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-4 and 6-9 are pending. Claims 1-4 and 6-9 are currently under consideration. All other claims have been canceled by Applicant.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated cDNA molecule encoding SEQ ID NO:16 (such as SEQ ID NO:15) or an isolated host cell, does not reasonably provide enablement for every isolated cDNA molecule that hybridizes under stringent conditions to SEQ ID NO:15 or a non-isolated host cell that comprises a transgenic primate or human in origin or could result from human genetic therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide adequate guidance or examples in order for an artisan to use the vast majority of nucleotide sequences that hybridize to SEQ ID NO:15 for the following reasons. First, the claim encompasses any length nucleotide sequence that could hybridize to SEQ ID NO:15, including tiny sequences made up of as little as two nucleotides. Such sequences have no use to the artisan as they are too small to encode a functional semaphorin protein or functional domain from said protein, and they are too small to be used as specific probes that could selectively hybridize and detect the presence of SEQ ID NO:15 because they would non-selectively hybridize to almost any nucleic acid in a biological sample. Second, many hybridizing sequences encompassed by the instant claim are not envisioned by the instant disclosure simply because said hybridizing sequences would not encode a functional semaphorin domain

or semaphorin protein and the specification does not contain adequate guidance, nor does it contain any working examples of what the artisan could use an encoding nucleotide sequence for when said sequence does not encode a semaphorin protein or a semaphorin functional domain. It would require undue experimentation with no predictable or even reasonable expectation of success given the teachings of the disclosure to enable the use of a nucleotide sequence that did not encode a semaphorin protein, a semaphorin functional domain, or a specific amino acid sequence that could be used to selectively identify a semaphorin protein because the claim is overly broad and is not commensurate with the disclosure which is drawn specifically to the making and using of semaphorin proteins and encoding sequences.

With regards to the host cell claims (claims 8-9), the claims encompass the cells of a transgenic animal *per se* (because all animals are made up of cells) such as a genetically altered primate, including humans (see page 18, lines 6-24 of the instant specification), which would include transgenic humans. The disclosure does not provide an adequate written description, guidance, or any working examples by which the genetic engineering or the gene therapy required to accomplish this could be reasonably placed into the hands of the public because of the well known difficulties and unpredictability of successfully performing this kind of gene therapy on primates, including humans. The technical hurdles to be overcome include the manufacture of a suitable genetic vector, adequate transfection of host tissue, adequate expression of the genetic vector, etc. The grounds of this portion of the rejection could be simply obviated by amending the claims to recite "an isolated host cell." In addition, if Applicant intends

to claim transgenic animals, the claims would be subject to a further restriction requirement as the examination of transgenic animals is beyond the scope of this examination and is a patentably distinct and separate invention from the instant invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims employ Markush language such as "drawn from the group consisting of" where no Markush group presently exists. Furthermore, claims 8-9 are indefinite because it is not clear if by host cell the Applicant is intending to claim isolated host cells *in vitro* or is trying to claim whole transgenic animals or both. Amending the claim to recite "isolated host cell" would obviate the grounds of this rejection. Finally, claim 3 is vague and indefinite because the specification does not provide a clear and specific definition of what "hybridizes under stringent conditions" is intended to mean. All of the definitions for hybridization conditions in the specification are open-ended; they include a recitation of specific hybridization conditions as an example only, and not as an absolute closed and specific definition. Because the metes and bounds of this product by process claim will vary depending upon the specific process used, i.e. the hybridization conditions (temperature, ionic strength, number of washings, etc.), the specific hybridization

conditions should be recited in the claim as a means to obviate the grounds of this particular rejection.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Püschel et al. Püschel et al., discloses a murine semaphorin C sequence (Figure 1 and pages 942 and 948) which has 62.2% overall identity and 82.3% best local similarity to instant SEQ ID NO:15 (see sequence comparison in this Office Action) which meets the limitation of claim 3 of hybridizing under stringent conditions considering that said stringent conditions are vague and undefined.

7. Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US 2003/0073129 A1, "Baker"). Baker discloses a human PRO1480 sequence and identifies it as a semaphorin (SEQ ID NO:252 and page 10) which has 98.7% overall identity and 99.9% best local similarity to instant SEQ ID NO:15 (see sequence

comparison in this Office Action) which would meet the claim limitations even if they were amended to recite the high stringency conditions taught in the instant specification.

8. No claims are allowed.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

December 4, 2004

Brenda Brumback

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